REMARKS

RESTRICTION REQUIREMENT UNDER 35 USC §121

The Applicants wish to begin by respectfully clarifying the actual, intended, and necessary operative scope of the claimed invention. In contrast to the Examiner's construction,[1] claim 1, for example, is properly construed (note the "comprising" language highlighted *infra*) to encompass methods to diagnose up to 38 different subtypes of human papilloma virus, simultaneously. This is *precisely the utility advantage of the current invention*. Otherwise if the claims were limited to two reagents at a time, for example, a patient at risk for cervical cancer would require 38^2 or 1,444 tests.

Particularly, the Applicants respectfully point out that, claim 1, for example, is drawn toward **a detector** for simultaneously detecting human papilloma virus selected from a Markush group of 38 different subtypes ***comprising***: a) a carrier ***comprising*** a first part and a second part for carrying said sample thereon; b) a first oligonucleotide corresponding to a deoxyribonucleic acid contained in a first subtype of human papilloma virus carried on said first part of said carrier; and c) a second oligonucleotide corresponding to a deoxyribonucleic acid contained in a second subtype of human papilloma virus carried on said second part of said carrier, wherein said first and second oligonucleotides are each selected from the specific group of oligonucleotides or a fully complementary sequence thereof.

None of the claims are drawn toward any of the oligonucleotides. The Markush group of oligonucleotides are

[1] The Examiner appears to construe claim 1 to be limited to methods and devices which employ merely 2 (two) oligonucleotides at a time. This is not the case. The device employs at least 2 (two) of the recited species or fully complementary versions thereof.

merely reagents for employment in the claimed device. The Applicants accordingly respectfully request the Examiner to withdrawal the restriction requirement.

CLAIM REJECTIONS

The Examiner has rejected Claims 1, 2, 5, and 13-16 under 35 U.S.C. §102(b).

Independent claims 1 and 13 have been amended, as recommended by the Examiner, to specifically require the recited oligonucleotides as reagents - or - species that are fully complementary thereto. Since the prior art does not teach the device and/or methods as now claimed which employ these species the Applicants respectfully request the Examiner to withdrawal the rejection.

The Examiner has rejected Claims 3 and 18 under 35 U.S.C. §103(a) in view of Van Doorn and Southern.

The Applicants respectfully point out that the combination of these references, however, does not meet the elements of a *prima facie* case under 35 USC §103(a). Particularly, to establish a *prima facie* case of obviousness, the prior art reference (or references when combined) must teach or suggest *all the claim limitations*. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991); MPEP §2142.[2]

[2] The Applicants also respectfully point out that a mere fact that references can be modified does not render the resultant combination obvious unless the prior art also suggests the modification. *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990). Accordingly, the teaching or suggestion to make the claimed invention, including the *specific* reagents now required by the Applicants' claims, and the reasonable expectation of success, must both be found in the prior art, *not based on the Applicants' disclosure*. See MPEP § 2143 - § 2143.03.

The language of claims 3 and 18 now presented require entities that are distinct from the prior art species.[3] Since these compositions of matter, *per se*, are not taught or suggested by either Van Doorn ***or*** Southern - a combination of these references cannot render the Applicants' claimed invention obvious under 35 USC §103(a).[4] Accordingly, the Applicants respectfully request the Examiner to withdrawal the rejection.

The Examiner has rejected Claim 17 under 35 U.S.C. §103(a) in view of Van Doorn and Bauer.

Similarly, the Applicants respectfully point out that the language of claims 17 now presented require oligonucleotide species as reagents that are independent and distinct entities from the prior art. See, *also*, footnotes 3 and 4, *supra*. Therefore the combination of these references, does not meet the elements of a *prima facie* case under 35 USC §103(a). Accordingly, the Applicants respectfully request the Examiner to withdrawal the rejection.

The Examiner has rejected Claims 18 and 19 under 35 U.S.C. §103(a) in view of Van Doorn and Hyldig-Nielsen.

Similarly, the Applicants respectfully point out that the language of claims 18-19 now presented require oligonucleotide species as reagents that are independent and distinct entities from the prior art species. Therefore the combination of these

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[3] All of the oligonucleotides recited by the Applicants in the claims, although not claimed as compositions of matter, are novel. These oligonucleotide species were each carefully designed and tested by the Applicants. Although several of the recited oligonucleotides may be *similar* to species in the prior art similar nucleic acids do not necessarily provide similar results in the disclosed device and methods of use therefor. The Applicants enclose herewith several peer-reviewed reports that illustrate, for example, nucleic acids that have only one base difference entirely change the specificity of species detection.

[4] Further, in contrast to Van Doorn which discloses oligonucleotides that originate from the middle of the HPV L1 gene, the claims now presented herein require the employment of oligonucleotides that originate from the end of the HPV L1 gene.

references, does not meet the elements of a *prima facie* case under 35 USC §103(a). Accordingly, the Applicants respectfully request the Examiner to withdrawal the rejection.

The Examiner has rejected Claims 1, 2, 5 and 13-17 under 35 U.S.C. §103(a) in view of Van Doorn, Bauer, and Orth; 3 and 18 further in view of Southern; and, 18 and 19 further in view of Hyldig-Nielsen.

The Applicants respectfully point out that a mere fact that references can be modified does not render the resultant combination obvious unless the prior art also suggests the modification. *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990). See, *also*, footnote 3, *supra*. Accordingly, even though Bauer, for example, may teach closely related probes, the teaching or suggestion to make the claimed invention, including the *specific* reagents now required by the Applicants' claims,[5] and the reasonable expectation of success, must both be found in the prior art, *not based on Applicants' disclosure*. See **MPEP § 2143 - § 2143.03**. Therefore the combination of these references, does not meet the elements of a *prima facie* case under 35 USC §103(a). Accordingly, the Applicants respectfully request the Examiner to withdrawal these rejections.

The Examiner has objected to certain subject matter of the Applicants' previous amendment (the subject matter of claims 13-19) (filed October 9, 2002) as new matter under. As a corollary, the Examiner has moreover rejected Claims 13-19 under 35 USC §112, ¶1.

[5] These specific oligonucleotides *precisely* provide the advantage of the current invention.

Particularly, the Examiner has alleged that SEQ ID NOs:651-688 are new matter. SEQ ID NOs:651-688, however, as recited in claim 13, corresponds to the same nucleic acid entities in the original disclosure (claim 13) identified by HPV subtype, NCBI Accession number, and loci.

The Applicants, pursuant to the Examiner's suggestion, include herewith a declaration under 35 USC §132 wherein it is stated that these sequences are in fact identical to the sequences that were present in the NCBI database at the time of the invention.[6]

Accordingly, the Applicants respectfully request, in view of the 37 CFR 1.132 Declaration now presented, that the Examiner withdrawal the objection under 35 USC §132, and the related rejection under 35 USC. §112, first paragraph.

* * *

For all the foregoing reasons, the Applicants submit that Claims 1-3, 5,and 13-20 are in condition for allowance. Early action toward this end is courteously solicited. *The Examiner is kindly encouraged to telephone the undersigned in order to expedite any detail of the prosecution*.

[6] Applicants therefore respectfully submit that the nucleic acid sequences do not constitute new matter because the original Claim 13, as filed, referred to the same sequences using the NCBI Accession Numbers of the sequences (e.g., www.ncbi.nih.gov) each of which was published at the time of the invention.

The Commissioner is authorized to charge any deficiency or credit any overpayment in connection herewith to Deposit Account No. 13-2165.

Respectfully submitted,

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Date: February 21, 2003

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Enclosures:

1. Appendix A (CLAIMS MARKED TO SHOW CHANGES)
2. Declaration of Dr. Tang-Yuan Chu Under Rule 1.132
3. Journal articles entitled:
   "DNA analysis and diagnostics on oligonucleotide microchips"; and

   "Large-Scale Identification, Mapping, and Genotyping of Single-Nucleotide Polymorphisms in the Human Genome"

CLAIMS MARKED TO SHOW CHANGES

1. (Twice Amended) A detector for simultaneously detecting and identifying at least one subtype of human papilloma virus (HPV) contained in a sample selected from the group consisting of (HPV 6, HPV 11, HPV 16, HPV 18, HPV 26, HPV 31, HPV 32, HPV 33, HPV 35, HPV 37, HPV 39, HPV 42, HPV 43, HPV 44, HPV 45, HPV 51, HPV 52, HPV 53, HPV 54, HPV 56, HPV 58, HPV 59, HPV 61, HPV 62, HPV 66, HPV 67, HPV 68, HPV 69, HPV 70, HPV 72, HPV 74, HPV 82, HPV CP8061, HPV CP8034, HPV L1AE5, HPV MM4, HPV MM7 and HPV MM8), comprising:

a) a carrier comprising a first part and a second part for carrying said sample thereon;

b) a first oligonucleotide corresponding to a deoxyribonucleic acid contained in a first subtype of human papilloma virus carried on said first part of said carrier; and

c) a second oligonucleotide corresponding to a deoxyribonucleic acid contained in a second subtype of human papilloma virus carried on said second part of said carrier,

wherein said first and second oligonucleotides are each selected from the group consisting of:
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13. (Twice Amended) A method for detecting at least one subtype of human papilloma virus DNA contained in a sample, comprising the steps of:

a) providing [an] at least one oligonucleotide about 15 to about 30 bases in length [, that is complementary to a DNA sequence] selected from the group consisting of (SEQ ID NO: 651, SEQ ID NO: 652, SEQ ID NO: 653, SEQ ID NO: 654, SEQ ID NO: 655, SEQ ID NO: 656, SEQ ID NO: 657, SEQ ID NO: 658, SEQ ID NO: 659, SEQ ID NO: 660, SEQ ID NO: 661, SEQ ID NO: 662, SEQ ID NO: 663, SEQ ID NO: 664, SEQ ID NO: 665, SEQ ID NO: 666, SEQ ID NO: 667, SEQ ID NO: 668, SEQ ID NO: 669, SEQ ID NO: 670, SEQ ID NO: 671, SEQ ID NO: 672, SEQ ID NO: 673, SEQ ID NO: 674, SEQ ID NO: 675, SEQ ID NO: 676, SEQ ID NO: 677, SEQ ID NO: 678, SEQ ID NO: 679, SEQ ID NO: 680, SEQ ID NO: 681, SEQ ID NO: 682, SEQ ID NO: 683, SEQ ID NO: 684, SEQ ID NO: 685, SEQ ID NO: 686, SEQ ID NO: 687, and SEQ ID NO: 688) or a fully complementary sequence thereof;

b) hybridizing said oligonucleotide with the DNA contained in said sample;

c) removing non-hybridized DNA contained in said sample; and

d) detecting a hybridization complex formed between said oligonucleotide and said DNA as indicative of the presence of said subtype of human papilloma virus contained in said sample.

20. (New) A detector for simultaneously detecting and identifying at least one subtype of human papilloma virus (HPV) contained in a sample selected from the group consisting of (HPV 6, HPV 11, HPV 16, HPV 18, HPV 26, HPV 31, HPV 32, HPV 33, HPV 35, HPV 37, HPV 39, HPV 42, HPV 43, HPV 44, HPV 45, HPV 51, HPV 52, HPV 53, HPV 54, HPV 56, HPV 58, HPV 59, HPV 61, HPV 62, HPV 66, HPV 67, HPV 68, HPV 69, HPV 70, HPV 72, HPV 74, HPV 82, HPV CP8061, HPV CP8034, HPV L1AE5, HPV MM4, HPV MM7 and HPV MM8), comprising:

a) a carrier comprising a first part and a second part for carrying said sample thereon;

b) a first oligonucleotide, corresponding to a deoxyribonucleic acid contained in a first subtype of human papilloma virus carried on said first part of said carrier, selected from within one of groups (SEQ ID NO:1-SEQ ID NO:12), (SEQ ID NO:25-SEQ ID NO:36), (SEQ ID NO:47-SEQ ID NO:58), (SEQ ID NO:69-SEQ ID NO:78), (SEQ ID NO:88-SEQ ID NO:97), (SEQ ID NO:107-SEQ ID NO:117), (SEQ ID NO:127-SEQ ID NO:137), (SEQ ID NO:148-SEQ ID NO:157), (SEQ ID NO:167-SEQ ID NO:178) , (SEQ ID NO:179-SEQ ID NO:189) , (SEQ ID NO:199-SEQ ID NO:209) , (SEQ ID NO:219-SEQ ID NO:229) , (SEQ ID NO:239-SEQ ID NO:250) , (SEQ ID NO:258-SEQ ID NO:269) , (SEQ ID NO:279-SEQ ID NO:288) , (SEQ ID NO:289-SEQ ID NO:298) , (SEQ ID NO:307-SEQ ID NO:316) , (SEQ ID NO:317-SEQ ID NO:327) , (SEQ ID NO:337-SEQ ID NO:347) , (SEQ ID NO:356-SEQ ID NO:366) , (SEQ ID NO:376-SEQ ID NO:386) , (SEQ ID NO:387-SEQ ID NO:397) , (SEQ ID NO:408-SEQ ID NO:418) , (SEQ ID NO:427-SEQ ID NO:444) , (SEQ ID NO:445-SEQ ID NO:455) ,

(SEQ ID NO:465-SEQ ID NO:476) , (SEQ ID NO:486-SEQ ID NO:497) , (SEQ ID NO:508-SEQ ID NO:520) , (SEQ ID NO:521-SEQ ID NO:532) , (SEQ ID NO:533-SEQ ID NO:541) , (SEQ ID NO:551-SEQ ID NO:562) , (SEQ ID NO:563-SEQ ID NO:574) , (SEQ ID NO:575-SEQ ID NO:585) , (SEQ ID NO:586-SEQ ID NO:596) , (SEQ ID NO:597-SEQ ID NO:607) , (SEQ ID NO:608-SEQ ID NO:617) , (SEQ ID NO:618-SEQ ID NO:627) , (SEQ ID NO:637-SEQ ID NO:646), or a fully complementary sequence thereof; and

c) a second oligonucleotide, corresponding to a deoxyribonucleic acid contained in a second subtype of human papilloma virus carried on said second part of said carrier, selected from within one of the groups (SEQ ID NO:1-SEQ ID NO:12), (SEQ ID NO:25-SEQ ID NO:36), (SEQ ID NO:47-SEQ ID NO:58),(SEQ ID NO:69-SEQ ID NO:78), (SEQ ID NO:88-SEQ ID NO:97), (SEQ ID NO:107-SEQ ID NO:117), (SEQ ID NO:127-SEQ ID NO:137), (SEQ ID NO:148-SEQ ID NO:157), (SEQ ID NO:167-SEQ ID NO:178) , (SEQ ID NO:179-SEQ ID NO:189) , (SEQ ID NO:199-SEQ ID NO:209) , (SEQ ID NO:219-SEQ ID NO:229) , (SEQ ID NO:239-SEQ ID NO:250) , (SEQ ID NO:258-SEQ ID NO:269) , (SEQ ID NO:279-SEQ ID NO:288) , (SEQ ID NO:289-SEQ ID NO:298) , (SEQ ID NO:307-SEQ ID NO:316) , (SEQ ID NO:317-SEQ ID NO:327) , (SEQ ID NO:337-SEQ ID NO:347) , (SEQ ID NO:356-SEQ ID NO:366) , (SEQ ID NO:376-SEQ ID NO:386) , (SEQ ID NO:387-SEQ ID NO:397) , (SEQ ID NO:408-SEQ ID NO:418) , (SEQ ID NO:427-SEQ ID NO:444) , (SEQ ID NO:445-SEQ ID NO:455) , (SEQ ID NO:465-SEQ ID NO:476) , (SEQ ID NO:486-SEQ ID NO:497) , (SEQ ID NO:508-SEQ ID NO:520) , (SEQ ID NO:521-SEQ ID NO:532) , (SEQ ID NO:533-SEQ ID NO:541) , (SEQ ID NO:551-SEQ ID NO:562) , (SEQ ID NO:563-SEQ ID NO:574) , (SEQ ID NO:575-SEQ ID NO:585) , (SEQ ID NO:586-SEQ ID NO:596) , (SEQ ID NO:597-SEQ ID NO:607) , (SEQ ID NO:608-SEQ ID NO:617) , (SEQ ID NO:618-SEQ ID NO:627) , (SEQ ID NO:637-SEQ ID NO:646), or a fully complementary sequence thereof; wherein said second oligonucleotide is

selected from a different group than that of the first oligonucleotide.

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